Remarks

Upon entry of the foregoing Amendment, claims 1, 3, 4-21, 24, 25 and 56-61 are pending in the application, with claims 1 and 56 being the independent claims. Claims 2, 22, 23, 26-55, 59, 60 and 62-91 were previously canceled. Claims 1, 21 and 24 are currently amended to clarify the claimed invention. Support for the amendment to claim 1 can be found, *inter alia*, at paragraphs [0089] and [0098] in the corresponding published application, US 2007/0128192 A1 ("the '192 publication"). Support for the amendment to claim 21 can be found, *inter alia*, in Example 5 of the '192 publication. Support for the amendment to claim 24 can be found, *inter alia*, in the claims as originally filed.

Objection to the Text of the Claims

The Examiner has indicated that the text of the claims as filed on June 1, 2009 is objected to because it is illegible in many places due to low quality resolution. *See* Office Action, page 2. Applications have herewith provided a legible listing of pending claims that will replace all prior versions of claims, and listings of claims in the application. Accordingly, Applicants respectfully request that the Examiner withdraw this objection.

Objection to the Oath/Declaration

The Examiner has objected to the oath or declaration stating that it is defective. *See* Office Action, page 2. Specifically, the Examiner has indicated that the oath or declaration does not clearly identify the mailing address of each inventor. *See id.* Applicants herewith submit an Application Data Sheet (ADS) for the current application

clearly indicating the mailing address of each inventor. The Examiner has further indicated that the oath has not been signed by inventor Minter. *See id.* Applicants respectfully note that the previously submitted oath was executed by inventor Minter. For the Examiner's convenience, Applicants provide herewith a copy of the fully executed oath/declaration previously filed on July 19, 2006. In view of the above, Applicants respectfully request that the Examiner withdraw this objection.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. *See* Office Action, page 3.

Regarding claim 1, the Examiner has noted that "there is insufficient antecedent basis for the limitation 'in Table 1' in the claims." *Id.* For clarification purposes, Applicants note that Table 1 is the Table numbered as such that begins on page 34. In the left-hand column of Table 1, names of various individually isolated IL-13 binding members are listed. Applicants have amended claim 1 to refer to "each set of CDRs present within the individual isolated IL-13 specific binding members listed in Table 1." Applicants further note that while antecedent basis may be required in certain instances, the use of a term for the first time in an independent claim does not necessarily require antecedent basis.

Regarding claim 21, the Examiner has indicated that "[i]t is unclear what the phrase 'the whole antibody is IgG4' means." *Id.* Applicants have herewith amended claim 21 to recite that "the whole antibody comprises IgG4." Thus, claim 21 should be

interpreted to refer to the IgG4 isotype of the claimed specific binding member comprising an IL-13 antigen-binding domain. In view of the amendments to the claims discussed above, Applicants respectfully request that the Examiner withdraw this outstanding rejection.

Rejection under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 1, 3, 7-21, 24 and 25 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action, page 3. Applicants respectfully traverse the rejection.

The test for the written description requirement is whether one skilled in the art can reasonably conclude that the invention has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); MPEP § 2163.02. The Federal Circuit has also emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicants 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed.'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000).

Applicants note that claim 1 is directed to an isolated specific binding member for IL-13 composed of an antigen binding domain comprising a ***set*** of CDRs, where the ***set*** of CDRs is selected from certain sets of CDRs as recited in claim 1.

To clarify claim 1 further, Applicants point out that a "set of CDRs," according to the invention, includes *all six* CDRs present within an antigen binding domain, *i.e.*, HCDR1, HCDR2, HCDR3, LCDR1, LCDR2, and LCDR3. Thus, the "BAK278D6 set of CDRs" refers to the entire set of all six CDRs of BAK278D6 where the HCDR1, HCDR2, HCDR3, LCDR1, LCDR2, and LCDR3 correspond to SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, and SEQ ID NO:6, respectively. *See* the '192 publication, paragraph [0068].

In view of the meaning of "set of CDRs" in the specification, the recitation in claim 1 of "a set of CDRs which contains one or two amino acid substitutions compared with the BAK278D6 set of CDRs" refers to an antigen binding domain that contains *overall* one or two amino acid substitutions *when considering the entire set of six CDRs together*.

The Examiner has stated that "the teachings of the instant specification nor the knowledge in the art are sufficient to demonstrate possession of the genus of antibodies encompassed by claim 1 and dependent claims thereof." Office Action, page 6. This statement appears to be based on an interpretation of claim 1 where the claim encompasses, *e.g.*, "a total of 11 amino acid residues with any amino acid substitution in each." *Id.* This, however, is not what claim 1 is intended to encompass. Claim 1 encompasses an isolated specific binding member for IL-13 composed of an antigen binding domain comprising a ***set*** of CDRs selected from a group consisting of the following sets of CDRs:

(1) the BAK278D6 set of CDRs;

(2) a set of six CDRs which contains one or two amino acid substitutions overall compared with the BAK278D6 set of six CDRs corresponding to the BAK278D6 set of CDRs, where the one or two amino acid substitutions can be made at one or two of the amino acid residues listed in claim 1 by their Kabat numbering position; and

(3) the set of CDRs present within any of the individual isolated IL-13 binding members listed in Table 1.

Applicants assert that the claimed invention satisfies the written description requirements of 35 U.S.C. § 112, first paragraph. Indeed, the Examiner himself has noted that Applicants are in possession of set (1) above, "the BAK278D6 set of CDRs, defined wherein the HCDR1 has the amino acid sequence of SEQ ID NO:1, the HCDR2 has the amino acid sequence of SEQ ID NO:2, the HCDR3 has the amino acid sequence of SEQ ID NO:3, the LCDR1 has the amino acid sequence of SEQ ID NO:4, the LCDR2 has the amino acid sequence of SEQ ID NO:5, the LCDR3 has the amino acid sequence of SEQ ID NO:6." Office Action, page 3 through page 4.

In addition, Applicants note that a representative number of species corresponding to set (2) discussed above, a set of six CDRs which contains one or two amino acid substitutions overall compared with the BAK278D6 set of six CDRs corresponding to the BAK278D6 set of CDRs, where the one or two amino acid substitutions can be made at one or two of the amino acid residues listed in claim 1 by their Kabat numbering position, are set forth in the specification. For example, Table 1 lists dozens of individual IL-13 binding members all of which contain at least one or two amino acid substitutions overall within their CDRs as compared to the BAK278D6 set of

CDRs at positions as recited. Thus, a representative number of molecules which fall within the scope of the genus has been provided that is sufficient to satisfy the written description requirement. *See Univ. of Calif. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997).

Finally, Applicants note that set (3) discussed above, the sets of CDRs present within the isolated specific binding members listed in Table 1, is set forth in the specification. As discussed above, Table 1 lists isolated specific binding members for IL-13. The sequences of the CDRs of the parental lineages have been provided in the specification, and any particular amino acid changes and the positions at which these changes are present within the CDRs are specifically set forth in Table 1. Thus, one of ordinary skill in the art, looking at the instant specification, would readily discern the sequences of this set of CDRs.

Regarding claims 24 and 25, the Examiner has stated that the claims require a composition comprising a specific binding member, antibody VH domain or antibody VL domain, and that the "specification provides no guidance or teaching that the Vh or VL domains encompassed by the instant claims have the necessary structure to bind IL-13 in the absence of a complimentary Vl or VH." Office Action, page 8. Without acquiescing to the rejection, Applicants herewith amend claim 24 such that the recited composition contains the specific binding member, or the pair of VH and VL according to claim 1.

In view of the above discussion, Applicants respectfully assert that the claimed invention satisfies the written description requirement of 35 U.S.C. § 112, first

paragraph. Accordingly, Applicants respectfully request that the outstanding rejections be reconsidered and withdrawn.

Consideration and allowance of all pending claims are respectfully requested.

Respectfully submitted,

Mita Mukherjee
Agent for Applicants
Registration No. 54,325

Date: February 16, 2010

MedImmune, LLC
One Medimmune Way
Gaithersburg, MD 20878